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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,206	02/09/2001	Michael Fritz	RDID0028US	5556

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/780,206

Applicant(s)

FRITZ ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 36-68 is/are pending in the application.
- 4a) Of the above claim(s) 42-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-41 and 68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants response to restriction (Paper No. 8) filed on June 19, 2002 has been entered.
2. Applicant's election with traverse of Group I (claims 36-41) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that search for all Groups I-II is not a serious burden on the examiner, which is found not persuasive since Group I and II claims are classified in different class and subclass as indicated in the restriction requirement (Paper No. 6). Further, (i) search of Group I will not necessarily reveal art relevant to Group II, because search of Group I is related to an apparatus comprising reagents and search of Group II is related to method of detecting a nucleic acid. Hence classification is the prima facie burden, which can not be rebutted; (ii) the issues are not the same with respect to 35 U.S.C. 112 and 35 U.S.C. 101 statutes, (iii) separate Art Units would examine the two Groups under ordinary circumstances. Therefore the restriction requirement is maintained herein. With regards to Group III, claim 68, drawn to an apparatus for amplifying nucleic acids, since Group I and III are classified in the same class and subclass, Group III is rejoined herein with Group I and claim 68 will be considered for examination.
3. Claims 39-41 and 68 in Groups I and III are considered for examination in this office action. Claims 42-67 are withdrawn from further consideration.
4. The disclosure is objected because of the following informalities:
  - (i) in Figure 4, sub title is phrased in non-english language. Correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are vague and indefinite because instant claim recite 'a binding space' / 'an amplification space' / and 'a detection space' which are unclear because whether the terms binding/ amplification/ detection spaces refer to accomplish for a chamber or vessel or tube in which all of the limitations (purification separation, amplification and detection) are included or all the limitations are separate from each other. Further the term binding is unclear because it is not clear whether binding space refers to nucleic acid collection space or hybridization space of nucleic acids, which refers to detection space. Amendment to clearly recite the terms would obviate the rejection.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 36-41 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al. (USPN. 5,856,174).

Lipshutz et al. teach an integrated nucleic acid diagnostic device or apparatus comprising (i) a nucleic acid binding space (extraction chamber) for purifying the nucleic acids by immobilizing nucleic acids and separating impurities (see column 4, lines 22-32, column 5, lines 25-67, column 6, lines 1-27); an amplification space (amplification chamber) for amplifying the nucleic acids comprising at least part of the binding space (see column 4, lines 22-32, column 7,

lines lines 65-67, column 8, lines 1-42); and a detection space for detecting amplified nucleic acids (see column 4, lines 22-32, column 8, lines 43-67, column 9, lines 1-28). Lipshutz et al also teach that the device comprises reagents for purifying, amplifying and detecting nucleic acids (see column 5, lines 44-48, column 7, lines 65-67, and column 8, lines 44-67, and column 8, lines 1-21); a capillary space (microcapillary channel) (see column 11, lines 59-67). The amplification chamber is miniaturized with heatable metal electrodes (see column 7, lines 33-48). Capillary space is glass (silicon) or other crystalline substrate (see column 12, lines 16-30). Thus the disclosure of Lipshutz et al. meets the limitations in the instant claims.

b. Claims 36-41 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Haff et al. (USPN. 5,827,480).

Haff et al. teach a capillary PCR instrument or apparatus comprising a capillary reaction vessel surrounded by a heatable metal exchanger (see column 3, lines 27-37, column 4, lines 4-30). Thus the disclosure of Haff et al. meets the limitations in the instant claim.

No claims are allowable.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned is 703-308-0294 for regular communications and - for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
July 18, 2002

  
JEFFREY FREDMAN  
PRIMARY EXAMINER